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Montana Board of Pharmacy

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A Friendly Reminder from Your Compliance Officer

By Bill Sybrant, Compliance Officer

Even though it is each practitioner's responsibility to ensure that he or she has taken care of his or her license or renewal, I would remind each owner or pharmacist-in-charge that he or she should not have any pharmacist or technician working in his or her employ that has not produced for verification and display his or her current license, registration, or renewal.

- For pharmacists and certified technicians, state renewal is June 30 of each year.
- Technicians in training have 18 months (nonrenewable) from the date of initial registration to complete certification.
- Pharmacy Technician Certification Board (PTCB) certification expires two years after it is issued, and is renewable every two years upon completion of 20 hours of continuing education (CE). You cannot maintain state registration without current PTCB certification.
- Interns must display registration at their place of work until they have completed all educational requirements and are licensed as a pharmacist.
- On November 30, certified pharmacy licenses, dangerous drug licenses, and technician utilization plan endorsements expire and must be renewed.
- Collaborative practice agreements must be renewed annually.
- Drug Enforcement Administration (DEA) licenses expire every three years and must be current to order, dispense, and have controlled substances at the facility.

As compliance officer, I will always check current facility and employee licenses and registrations during compliance visits. If any license or registration is not current and available for inspection, the pharmacy may be forced to close or the individual licensee may be forced to cease his or her shift. All findings will be reported to the Montana Board of Pharmacy and applicable authorities. Thanks for your help in ensuring that all licenses and registrations are posted and current.

Revisions to Naturopath's Formulary

In the 1990s the Montana Legislature allowed limited prescriptive authority to naturopaths and allowed for the establishment of a "Natural Substance Formulary List." The current list from which naturopaths may prescribe can be found on the Board of Alternative Health Care's Web site, www.discoveringmontana.com/dli/bsd. The "Natural Substance Formulary List" can be found under the "rules" section at 24.111.511. In December 2004 the Board of Pharmacy sent written testimony to the Board of Alternative Health Care regarding several proposed additions to the "Natural Substance Formulary List." At that time the Board of Pharmacy questioned the proposed addition of wholly synthetic or semi-synthetic prescription drug products such as fluconazole, ketoconazole, azithromycin, Augmentin®, and oxycodone to the existing list of "natural" substances, and suggested several standard references to define "natural" versus synthetic and semi-synthetic drug products. The Board of Alternative Health Care has not yet finalized its revision, and the Board of Pharmacy will consider the matter further on April 13-14, 2005, in Helena, MT.

Montana Pharmacists Recovery Network Reminder

Confidential assistance for anyone needing help or having concerns about drug- or alcohol-related problems involving himself or herself, a colleague, an employer, employee, or family member can be found by calling toll-free at 1-888/322-9674. Your call will be answered by a pharmacist who can give you confidential guidance or referral. One out of every three pharmacists is likely to come into contact with a chemically dependent pharmacist during his or her professional lifetime. The Pharmacists Recovery Network serves as a confidential lifeline to those professionals.

Board of Pharmacy Web Site Update

A direct link to the National Association of Boards of Pharmacy® (NABP®), DEA, Montana Pharmacy Association, and Office of Inspector General (Health Insurance Portability and Accountability Act questions) can be found under "Related Internet Links" on the right pull-down menu of the Board's Web site, www.discoveringmontana.com/dli/pha. A separate new link to the DEA Pharmacist's Manual can also be found there. The Pharmacist's Manual is helpful in providing quick answers to controlled substance questions. A link to DEA's rationale on its position reversal on multiple C-II prescriptions

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Accutane, Palladone RMPs Designed to Protect Patient Safety

Risk Management Programs (RMPs) are developed by drug manufacturers to meet the requirements of FDA's drug approval process, in conjunction with FDA, to minimize risks associated with specific drug products. To date, several specific drug products have formal risk management programs beyond labeling alone, to further ensure patient safety. Two relevant examples are Accutane® (Roche Pharmaceuticals) and Palladone Capsules (Purdue Pharma LP).

Accutane

On November 23, 2004, FDA announced changes to the RMP for isotretinoin (Accutane) that will be implemented in mid-2005 in order to reduce the risk of birth defects associated with fetal exposure to the medication. All of the manufacturers of isotretionin have entered into an agreement with Covance, a drug development services company that currently coordinates the registry for Celgene's thalidomide. Covance's task is to develop and operate a universal enhanced RMP by mid 2005; this program will require patients, dispensing pharmacists, and prescribers to register in a single, centralized clearinghouse. The program will also mandate that a pregnancy test be performed at certified laboratories instead of home or in-office testing. According to the Accutane RMP, System to Manage Accutane Related Teratogenicity, when the registry denies an authorization to fill the prescription, the prescribing physician must explain the reason for denial to the patient; FDA specifically states that the physician is responsible for informing a woman if a pregnancy test result comes back positive.

Palladone

Due to Palladone's (hydromorphone hydrochloride) high potential for abuse and respiratory depression, the drug's manufacturer, Purdue Pharma LP, in conjunction with FDA, developed an RMP for this new extended-release analgesic. Introduced to the market in January 2005, Palladone is approved for the management of persistent, moderate to severe pain in patients requiring continuous, around-the-clock analgesia with a high potency opioid for an extended period of time (weeks to months) or longer. Palladone is to be used in patients who are already receiving opioid therapy, who have demonstrated opioid tolerance, and who require a minimum total daily dose of opiate medication equivalent to 12 mg of oral hydromorphone.

The analgesic's RMP was devised with four goals:

1. Facilitation of proper use (patient selection, dosing)
2. Avoidance of pediatric exposure
3. Minimization of abuse, and
4. Reduction of diversion

Palladone's RMP includes provisions for understandable and appropriate labeling, and proper education of health care professionals, patients, and caregivers. In addition, the manufacturer has offered training sessions to its sales representatives. The RMP provides for the observation and surveillance of abuse and, if abuse, misuse, and/or diversion occur, this program includes an array of interventions. A Medication Guide will be distributed to patients prescribed Palladone.

During the initial 18 months of Palladone's release to the market, the manufacturer will only promote Palladone to a limited number of medical practitioners experienced in prescribing opioid analgesics and will closely monitor and gather data on Palladone's use and any incidences of abuse or diversion, and report this information to FDA on a regular basis.

Metronidazole and Metformin: Names Too Close for Comfort

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

A family practice physician in a community health center prescribed metformin 500 mg b.i.d. to a newly diagnosed diabetic man from India who did not speak English. When the patient returned to his office a few months later, he brought his medications with him, as requested. His physician quickly noticed that metformin was missing. Instead, the patient had a prescription bottle labeled as metronidazole with directions to take 500 mg twice a day. The prescription had been refilled several times. Luckily, the patient's diabetes remained stable, and he seemed to suffer no adverse effects from two months of unnecessary antimicrobial therapy. The physician notified the pharmacy of the error and asked the pharmacist to check the original prescription, which had been written clearly and correctly for metformin. Upon further investigation, the pharmacist found that the computer entry screen for selecting these medications included "METF" (for metformin) and "METR" (for metronidazole). Apparently, one of the pharmacy staff members had entered "MET" and selected the wrong medication that appeared on the screen.

In another community pharmacy, the same mix-up happened twice, one day apart. In one case, metformin was initially dispensed correctly, even though the prescription had been entered incorrectly as metronidazole – again, when the wrong mnemonic was chosen. The pharmacist who filled the prescription clearly understood that the physician had prescribed metformin, so he filled the prescription accordingly. However, he failed to notice the order entry error, as he did not compare the prescription vial label to the drug container label. Unfortunately, the initial order entry error led to subsequent erroneous refills of metronidazole, as stated on the label. In the other case, bulk containers of the medication were available from the same manufacturer, both with similar highly stylized labels. Thus, confirmation bias contributed to staff 's selection of the wrong drug. After reading "MET" and "500" on the label, the staff member believed he had the correct drug.

In a hospital pharmacy, metronidazole 500 mg and metformin ER 500 mg were accidentally mixed together in the metronidazole storage bin. This resulted in dispensing metformin instead of metronidazole. Fortunately, a nurse recognized the error before giving the patient the wrong medication. Both were generic products, although the brands Flagyl® (metronidazole) and Glucophage®

(metformin) are also available. Unit-dose packages of these drugs contain bar codes, and the printed information is very small, which adds to their similar appearance.

Metronidazole-metformin mix-ups could be serious, considering the different indications and the potential for drug interactions. To avoid selecting the wrong drug from the screen, consider programming the computer to display the specific brand names along with the generic names whenever the "MET" stem is used as a mnemonic. To reduce similarity of the containers, purchase these medications from different manufacturers. Another option in hospital settings is to stock only the 250 mg tablets of metronidazole, since metformin is not available in that strength. This option allows a small risk for nurses who may administer just 250 mg when 500 mg is prescribed, but the potential for harm from giving the wrong drug is greater.

It is also a good idea to separate the storage of these products. During the dispensing process, drug names listed on written prescriptions and hospital orders should be matched to computer labels and manufacturers' products. Since metformin is used to treat a chronic condition, and metronidazole is more likely to be used for an acute condition, outpatient refills for metronidazole are less common and, therefore, bear a second look. Asking physicians to include the drug's indication on the prescription can also help prevent errors.

We have asked FDA to add these drugs to the list of nonproprietary names that would benefit from using "Tall Man" letters. Meanwhile, underline or highlight the unique letter characters in these drug names to make their differences stand out.

'Dietary Supplements' Contain Undeclared Prescription Drug Ingredient

In early November 2004, Food and Drug Administration (FDA) cautioned the public about the products Actra-Rx and Yilishen, which have been promoted via the Internet. These products, purported as "dietary supplements" to treat erectile dysfunction and enhance sexual performance, were actually found to contain the active prescription drug ingredient, sildenafil, the active drug ingredient in Viagra®, which is approved in the United States for the treatment of erectile dysfunction.

The *Journal of the American Medical Association* (*JAMA*) published a research letter that explained the results of a chemical analysis that found that Actra-Rx contained prescription strength quantities of sildenafil. FDA conducted its own analysis, the results of which corroborated the analysis published in *JAMA*.

Sildenafil is known to interact with a number of prescription medications. For example, sildenafil may potentiate the hypotensive effects of medications containing nitrates, which are commonly used to treat congestive heart failure and coronary artery disease.

FDA instructed those who are taking Actra-Rx and/or Yilishen to stop and consult their health care provider and warned that the use of these products could be dangerous to patients' health.

For more information, please visit the following Web site: www.fda.gov/bbs/topics/ANSWERS/2004/ANS01322.html.

NABP Releases Criteria for National Specified List of Susceptible Products, Adds One Drug to List

In late 2004, the National Association of Boards of Pharmacy® (NABP®) Executive Committee finalized the criteria that detail standards and guidance for NABP's "National Specified List of Susceptible Products" (List) based upon recommendations made by NABP's National Drug Advisory Coalition (NDAC). Also, in accordance with NDAC's recommendation, the Executive Committee decided to include Viagra® (sildenafil) on NABP's List. NABP's List, which the Association first released in early 2004, was created to help states reduce redundancy and represented a starting point for states that had an imminent need for such direction. In addition, by adopting NABP's List, states collectively would be able to recognize one national list instead of potentially 50 different lists.

The NDAC is a standing committee that was appointed by NABP's Executive Committee in accordance with the updated Model Rules for the Licensure of Wholesale Distributors, which is a part of the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*. The Model Rules were released by the NABP Task Force on Counterfeit Drugs and Wholesale Distributors, with the aid of representatives from the pharmacy profession, government, and the wholesale distributor industry, to protect the public from the ill effects of counterfeit drugs and devices. In addition to stricter licensing requirements such as criminal background checks and due diligence procedures prior to wholesale distribution transactions, the Model Rules mandate specific pedigree requirements for products that are particularly prone to adulteration, counterfeiting, or diversion. These products, as defined in the updated Model Rules, are designated as the "National Specified List of Susceptible Products."

The updated "National Specified List of Susceptible Products" is available on NABP's Web site at www.nabp.net. NABP's List criteria that detail standards and guidance (eg, under what circumstances a product will be considered for addition to NABP's List) are also available on the Association Web's site and detailed in the February 2005 *NABP Newsletter*.

FDA Announces New CDERLearn Educational Tutorial

The US Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) recently announced that its new online educational tutorial "The FDA Process for Approving Generic Drugs" is now available at http://www.connectlive.com/events/genericdrugs/.

This seminar provides viewers with an overview of FDA's role in the generic drug process. The tutorial also discusses various aspects of the Abbreviated New Drug Application (ANDA) process, including how FDA's approval assures that generic drugs are safe, effective, and high quality drug products.

This program meets the criteria for up to one Accreditation Council for Pharmacy Education contact hour (or 0.1 CEU).

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can be found under "Recent News" on the right pull-down menu on the Web site. The Montana Board of Pharmacy has written a letter of concern regarding this policy reversal to DEA, and has been joined in the effort by several other boards of pharmacy and NABP. Some medical boards are also involved. Until the matter is resolved, it is wise to encourage practitioners to avoid writing multiple C-II prescriptions for their patients with stable medication requirements with the notation, "Do not fill before. . ." on each blank. Post-dating of any prescription (representing the actual date of writing as one or two months into the future) remains illegal, as a prescription is a legal document and should always be dated as of the date on which it was written.

Kudos to Our 50-Year Pharmacists

By Rebecca "Becky" Deschamps, Executive Director
Six Montana pharmacists received their first license to practice 50 years ago. Three of these pharmacists still have active licenses, and two of the three are listed as preceptors.The 2005 50-year pharmacists are Eugene Edward Chieslar #1970, Walter B. Fellows #1973, Richard R. Fuller #1980, William Jay Johnson #1978, Mary Joyce Keast #1969, and June Baney Woffenden #1968. The Board thanks them for being positive examples and mentors to so many of us. Walter Fellows graduated from the Montana State University (MSU) School of Pharmacy when it was a four-year program, and recalls that no formal internship program was in place at that time. He wanted to practice in Montana, but the only positions available paid barely $300 per month. With three small children, Walter and his wife moved to South Dakota, where he earned $325 per month. One of his children, Tricia Campbell of Polson, MT, followed in her father's footsteps and became a pharmacist as well. The family eventually returned to Montana, and Walter has continued to practice until fairly recently. He has enjoyed pharmacy greatly and commented that he has seen massive changes in our profession in the last 50 years. One thing he noted has not changed: "We need to do much better with patient counseling."

Mary Joyce Keast attended MSU's School of Pharmacy as well, and was one of six women in the entire pharmacy program. A hospital practitioner at heart, she worked at Sacred Heart Hospital in Spokane, WA, for several years before returning to practice in Montana. Although she had passed her board examinations in Washington and practiced pharmacy there, she recalls that the Montana Board at that time looked with some degree of suspicion at hospital practice and asked her to work for another year in Montana before becoming licensed in our state. Her brief experiences in community pharmacy were memorable – she once sold a box of Russell Stover® chocolates to someone for a gift, only to receive a terse call stating that she had sold the display box containing perfect-looking chocolates that were unfortunately rubber, and asking if that was some sort of joke. She has thoroughly enjoyed her many years of hospital pharmacy practice, and the scheduling flexibility she enjoyed when her children were young.

Take some time out of your busy day to thank these pharmacists and others who have been your mentors for the fine examples they have set in your own professional life. Harriett Roscoe Dooling, Bess Muskett, Mary Joyce Keast, Tony Francisco, Dick Richards, Don Peterson, Frank Pettinato, Frank Davis, Trygve Brensdahl, Herman Schroeder, and Tom Mensing have been my mentors over the years. I'd like to give them my heartfelt thanks.

It Is Nearly That Time of the Year Again

Pharmacist and pharmacy technician renewal notices will go out within the next few weeks, and are due on or before June 30. You may not practice after that time if you have not renewed your license. Pharmacists need 15 hours of Acreditation Council for Pharmacy Education-, Continuing Education Advisory Council-, or Continuing Medical Education-approved CE each year, five hours of which must be in a group setting. Interactive CE that qualifies as group credit is also available online. Ten percent of pharmacists are audited for CE credits each year, and that group is randomly chosen by computer.

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